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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,296	06/21/2001	Thomas E. Tarara	0054.10	6348

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INHALE THERAPEUTIC SYSTEMS, INC
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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 12/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/886,296	TARARA ET AL.
	Examiner	Art Unit
	Sharmila S. Gollamudi	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 September 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4-15, 18-23, 39-47 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 4-15, 18-23, 39-47 and 49-51 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Amendment C and Information Disclosure Statement received on September 27, 2002 is acknowledged. Claims 4-15, 18-23, 39-47, and 49-51 are included in the prosecution of this application. Claim 48 is cancelled.

New Rejections in Light of Amendments

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4-15, 18-23, 39-47, 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanes et al (US 5855913, cited prior art) in view of Cohen et al (5149543) by themselves, or in further view of Yen (5308620, cited prior art).

Hanes et al teach aerodynamically light particles for drug delivery to the pulmonary system. The particles have a tap density of less than 0.4 g/cm³ and a diameter between 5 to 30 microns (Note abstract). Hanes teaches features such as irregular surface texture and porous structure contribute to low tap density and manipulation of these features permits the delivery of larger particle envelope volumes into the lungs (col. 9, lines 10-25). Further, low tap density particles are taught to have small aerodynamic diameter (instant diameter) (col. 9, lines 26-45). The particles contain surfactants such as DPPC (instant gel to liquid temperature) and the microstructures are taught to encapsulate active agents, which allows the active to remain protected (col. 10, lines 37-50 and examples). Polysaccharides, polymers of acrylic acids and methacrylic acids may be used to make the microsphere. Further, the

particles may be formed into microspheres by methods such as coacervation, interfacial polymerization, etc. (note col. 6).

Hanes et al do not teach the use of calcium in the structural matrix or instant pore size.

Cohen et al teach a method of making microspheres. The method is based on the use of water-soluble polymers with charged sides that are crosslinked with multivalent cations (abstract). Suitable polymers that are reacted with cations are polyacrylic acids, polymethacrylic acid, PCPP, etc (col. 4, lines 1-5). The cations taught are calcium, copper, magnesium, etc (col. 6, line 22).

Yen teaches the method of making stable, porous nanomatrixes. Yen teaches the advantages the porous nature of a carrier vesicle such as this structure allows the substrate of the biologically active molecules to diffuse into the interior of the nanomatrix and for the reaction products to diffuse out. The drugs can also diffuse out of the nanomatrix at rates dependent on the porosity of the nanomatrix carrier. (Note col. 8, lines 34-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hanes and Cohen since Cohen teaches the method of making microspheres thorough coacervation using cations such as calcium. One would be motivated to do so with the expectation of similar results since Hanes teaches the use of polymers with charged sides such as polyacrylic acids, etc. and teaches that any process of making the microsphere is suitable.

The manipulation of tap density and pore size are deemed obvious to one of ordinary skill in the art since Hanes teaches the manipulation of surface roughness (porosity), diameter, and tap density determine the delivery site of the particles (col. 8, lines 19-68). Therefore, one would be motivated to manipulate the factors and fabricate the microstructure according to the region to be targeted. Further, motivation to manipulate the pore size is to control the rate of the release of actives from the carrier as taught by Yen; therefore depending on the drug used and the desired rate of release, one would be motivated to manipulate its size.

Claim 51 under 35 U.S.C. 103(a) as being unpatentable over Hanes et al (US 5855913) in view of Cohen et al (5149543) in further view of Igarashi et al (4201774).

As set forth above, Hanes et al teach dry powder inhaler compositions. Hanes teaches several active agents including antibiotics in the composition.

Hanes does not teach the specific use of aminoglycoside antibiotic.

Igarashi et al teaches aminoglycoside antibiotics for the treatment of gram-positive and gram-negative bacteria. Further, the reference teaches the use diluents such as calcium carbonate for the composition and the composition in a form of an inhalant (col. 5, lines 19-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the instant medicament in Hanes et al's composition. One would be motivated to do so since the instant antibiotics treat gram-positive and gram-

negative bacteria and depending on the patient's requirement, the appropriate drug is used.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG
MGM
December 4, 2002

Michael G. Hartley
MICHAEL G. HARTLEY
PRIMARY EXAMINER